JUL 25 2001 S S+E K001508

IV. DEVICE NAME

A) Proprietary Name: *Hyalomatrix™ KC WOUND DRESSING*

B) Common Name(s):

1) Synthetic Polymer wound and burn dressing
2) Synthetic Polymer graft dressing

C) Classification name: non interactive wound and burn dressing
The applicable product code for this unclassified device is MGP.

V. REGISTRATION NUMBER

A)	Establishment Registration Number:	None
B)	Establishment Name and Address:	Fidia Advanced Biopolymers Via Ponte della Fabbrica 3/A 35031 Abano Terme (Padova) ITALY
C)	Contact Person:	Paolo Rampazzo, Manager Quality Assurance
	1) Telephone:	+39-049-823-2416
	2) Fax	+39-049-823-2752
	3) e-mail	prampazzo@fidiapharma.it

VI. DEVICE CLASSIFICATION

DEVICE CLASSIFICATION OR CATEGORY

A) The subject device is an unclassified device. This determination is based on research of publicly available information concerning substantially equivalent devices currently being marketed for the same indications and intended use. The determination that the device is unclassified is also based on the "Draft Guidance for the preparation of a premarket Notification for a Wound and Burn Dressing" issued March 31, 1995. Based on the classification of the device and its intended use as a wound and burn dressing, F.A.B. believes it is appropriate for this device to be reviewed by the Division of General and Restorative Devices within the Center for Devices and Radiological Health. The generic device type is presently classified as a unclassified device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2001

Mr. Paolo Rampazzo
Manager, Quality Assurance
Fidia Advanced Biopolymers S.r.l
Via Ponte Della Fabbrica, 3/A
35031 Abano Terme (PD)
Italy

Re: K001508
Trade/Device Name: Hyalomatix™ KC Wound Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: April 23, 2001
Received: April 26, 2001

Dear Mr. Rampazzo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001508

Device Name: Hyalomatrix™ KC Wound Dressing

Indications for Use: The FAB Hyalomatrix™ KC Wound Dressing is indicated for the management of wounds in the granulation phase such as pressure ulcers, venous and arterial leg ulcers, diabetic ulcers, surgical incisions, second degree burns, skin abrasions, lacerations, partial-thickness grafts and skin tears, wounds and burns treated with meshed grafts. It is intended for use as a temporary coverage for wounds and burns to aid in the natural healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

B Mitchell 8/10/01

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K001508